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### REMARKS:

The Specification has been amended. No new matter has been added. All Claims listed throughout the prosecution history of the instant Application are presented. Claims 30-32 are amended.

### **Objections to the Specification**

In regards to the SEQ ID NO:s, the Examiner is directed to the Specification and sequence listing as filed. As originally filed SEQ ID NO: 1 to 15, SEQ ID NO:1a to 5a and SEQ ID NO:1b to 11b were submitted. Said sequences were alter reorganized as SEQ ID NO: 1 to 31. Subsequently, in July 11, 2003, Applicants filed a new sequence listing comprising the original SEQ ID NO:1 to 15 and the former SEQ ID NO:17, 18, 25 and 28 which renumbered the sequences from SEQ ID NO:1 to 19. Thus, for example, originally filed SEQ ID NO:17 is presently SEQ ID NO:16. Later, Applicants added the primers disclosed in the Specification as originally filed as SEQ ID NO:20 and 21. Accordingly, the entered sequence list of SEQ ID NO:1 to 21 accurately reflects those of the instant application.

The Examiner Objection to the July 13, 2003, response regarding SEQ ID NO:12 has been addressed in an new amendment.

Applicants assert that all of the Examiner's Objections have been overcome and favorable action is solicited.

### **Rejections under 35 USC §112 ¶1**

Claims 30-32 are rejected under 35 USC §112 ¶1 for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with it is most nearly connected, to make and/or use the invention.

In regards to all the 112 ¶1 rejections, it must be remembered that to satisfy the written description prong of 35 USC §112 ¶1, the Specification must only describe the invention in sufficient detail so that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). No particular form of disclosure is required, but "the description must clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed." *In re Gosteli*,

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872 F.2d 1008, 1012 (Fed. Cir. 1989) (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

The MPEP states that a "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" and as such, a single species may be enough to identify the entire genus (see MPEP 2163.II.A.3.a.ii.). While *Lilly* (referenced by the Examiner) does provide suggestions for how to describe a genus, a more recent Federal Circuit case provides further instructions regarding written description requirements. When discussing what is required for a written description the court said "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution" (*Capon v. Eshhar*, 418 F.3d 1349, 1358; 2005). In overturning a BPAI decision, which relied on similar rejections reasons as stated in the instant Office Action, where both parties to an interference had all Claims in their respective patents cancelled for failing to meet the written description requirement, the court stated that "[t]he Board erred in refusing to consider the state of the art of the scientific knowledge" and when citing *Lilly* and *Fiers* spoke of a rulings in view of a "wish" list provided in said inventions, and not the state of the relevant art (*Id.* at 1357). Further, the court stated, that "[i]t is not necessary that every permutation with a generally operable invention be effective in order for an inventor to obtain a generic claim" and that both parties supported because they "present[ed] not only general teachings... but also specific examples" §112 (*Id.* at 1359).

Applicants assert that the instant Specification fully complies with these requirements because it allows one of ordinary skill in the art to practice the instant invention. Applicants provide in the instant Specification summary information such as the function of PDAT and general nucleotide isolation techniques which meet the "general teachings" prong. Further, Applicants have supplied five additional sequences of PDAT genes which provide "specific examples" of the instant invention. Accordingly, for at least the reasons described above, the instant Application does provide an adequate written description for one of ordinary skill in the art to practice the instant invention and withdrawal of the instant rejections is respectfully requested.

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Regarding the enablement requirement of §112, the Federal Circuit has held that "[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation'." (*Amigen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. (2003))). The Claims as currently amended are fully enabled by the Specification of the instant application in combination with the general knowledge of one of ordinary skill in the art.

As described in *Capon*, as the skill in the art progresses so does the analysis of the inventions in said art. The Examiner alleges that the instant disclosure presents no guidance or working examples of the use of the genus of transgenic cells and transgenic organisms or genus of nucleotides included in the scope of the claims. Applying *Capon* and the relative state of the art at the time of filing, one of ordinary skill would be able to create the working examples the Examiner asserts are lacking. The skill in the art at the time of filing was such that creation of transgenic organisms, in general, was routine.

Applicants emphasize again that the instant invention is a process for the production of triacylglycerol, comprising growing a transgenic cell or transgenic organism, whereby said synthesis occurs because said enzyme catalyzes in an acyl-CoA-independent reaction the transfer of fatty acids from phospholipids to diacylglycerol especially uncommon fatty acids.

Further, the Examiner need only look to the USPTO itself for references for the screening that allegedly cannot occur. The numerous Affymetrix patents clearly show that large scale screening was and is state of the art and that a comparison of a sufficient number of sequences of PDATs to the disclosed PDATs can be performed; no undue experimentation would be required. Moreover, computational techniques were available at the time of filing for structural predictions based on sequence listings. (See e.g., The Boston University Protein Sequence Analysis server available at <http://bmerc-www.bu.edu/psa/>). Thus, a skilled artisan would have been able to make a prediction on the structure of a PDAT gene so as to make them in light of the disclosure of the instant invention.

**Rejections under 35 USC §112 ¶2**

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Claims 30-32 are rejected under 35 USC §112 ¶2 for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree.

Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the Claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more. (*See Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, (Fed. Cir. 1993)).

While not conceding the correctness of the Examiner's reasons for rejection and in order to facilitate timely prosecution, Applicants have amended Claims 30-32. All of the Examiner's concerns have been addressed. Accordingly, Applicants assert that the instant Claims, when read in light of the instant Specification, are definite and respectfully request withdrawal of the instant rejection under 35 USC § 112. Favorable action is solicited.

#### Rejections under 35 USC §102

Claim 30 is rejected for allegedly being anticipated by Yu et al. Applicants respectfully disagree and request reanalysis of the previously submitted arguments.

Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). The identical invention must be shown in as complete detail as it is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants reemphasize that the cited art teaches an CoA dependent acyltransferase which transfers acyl to sterol and fails to teach where an enzyme catalyzes in an acyl-CoA-independent reaction the transfer of fatty acids from phospholipids to diacylglycerol in the biosynthetic pathway for the production of triacylglycerol.

Accordingly, Since Yu et al. does not teach each and every element of the instant Claims, it does not anticipate the instant invention. Applicants therefore respectfully request withdrawal of the rejection under 35 USC § 102(b). Favorable action is solicited.

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Applicants respectfully submit that for at least the reasons listed above the rejections under 35 USC §112, first and second paragraphs and 35 USC 102(b) should be withdrawn and an indication of allowance should appear in the next paper from the Office. Favorable action is solicited.